

REMARKS

Claims 1 and 3-20 are pending in the application. Claims 1 and 3-20 are rejected. No claims are allowed.

As noted by the Examiner, claim 2 was incorrectly cancelled in Applicants' previous submission. The subject matter of claim 3, not claim 2, was incorporated into claim 1. Accordingly, claim 3 is now cancelled, and the subject matter of cancelled claim 2 has been incorporated into newly added claim 21. The dependencies of claims 9-11 have been changed accordingly.

No new matter has been introduced by this amendment.

Claims 1 and 4-21 are presented for further consideration. Reconsideration of the claim rejections and allowance of the pending claims in view of the following remarks are respectfully requested.

Claim Objections

Claims 9-11 are objected to as depending from cancelled claim 2. As noted above, the subject matter of cancelled claim 2 has been incorporated into newly added claim 21, and the dependencies of claims 9-11 have been changed accordingly. Withdrawal of the objection is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 3-9 and 12-18 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Close et al., EP 0094116 ("Close") for the reasons of record.

Claim 3 has been cancelled, thereby rendering the rejection with respect to this claim moot. Regarding the remaining claims, Applicants maintain that Close does not disclose the claimed invention.

As explained in Applicants' previous submission, Close discloses analgesic compositions, such as those containing aspirin, that have enhanced dissolution in the intestinal tract. Specific compositions have aspirin and excipients in an active core; a coating over the core containing an active ingredient (e.g., additional aspirin) and an optional "dispersing aid," which assists in disrupting a coating in the environment of the intestines; and an outer enteric coating. The Examiner states in the Response to Arguments section of the Office Action that "Close teaches that antihistamines can be present (see page 4, line 27), which is one of the instantly claimed acid sensitive pharmaceutically active ingredients." Although Close does suggest that antihistamines may be present, it is only one of a laundry list of "optional components" that may be included in the active core. None of the Examples in Close employ an antihistamine. Equally as important, the instant claims require an acid-sensitive pharmaceutically active ingredient. Applicants submit that the disclosure of a broad genus of antihistamines does not place the public in possession of only those antihistamines that are acid-sensitive. This is particularly true in this case, where the formulations in Close provide aspirin in contact with an enteric coating, and thus are not intended to protect acid-sensitive pharmaceutically active ingredients.

Accordingly, Applicants maintain that claims 1, 4-9 and 12-18 (as well as newly added claim 21) are not anticipated by Close, and reconsideration of this basis for rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 10, 11, 19 and 20 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Close in view of Henriksen et al., US 6,391,342 ("Henriksen") for the reasons of record.

Applicants maintain that Close in view of Henriksen would not have suggested the claimed invention. As explained in Applicants' previous submission, Henriksen discloses preformed cores coated with a layer comprising a benzimidazole compound, a disintegrant and a surfactant in a matrix of a melt essentially consisting of one or more esters of glycerol and fatty acids. An intermediate coating layer is provided for protecting the active ingredient from an outer enteric coating. Materials which may be used in intermediate layer include HPMC, HPC and PVP. Henriksen does not contemplate the use of an alkaline substance in the disclosed formulations. Indeed, Henriksen specifically states at column 5, lines 38-40: "When this technique is used in accordance with the invention, there is no need to use any alkaline compounds or salts for further stabilization of the benzimidazole."

The Examiner states in the Response to Arguments section of the Office Action that Close teaches that "Close is the primary reference, and Henriksen is relied upon as a secondary reference to modify Close. In said combination, it would have been obvious to one of ordinary skill to utilize the benzimidazole

proton pump inhibitor of Henriksen in the invention of Close to allow for the composition of Close to be utilized to treat a broader range of disorders, and Henriksen teaches that the active of Henriksen requires an intermediate layer, which is the same as the coating system of Close."

Essentially, the Examiner is asserting that one of skill in the art would have sought to replace the aspirin in the formulations of Close with a benzimidazole compound. Applicants submit that there is no rationale basis for doing so. The whole basis for the invention in Close is to provide an enteric coating on an NSAID to protect a patient's stomach. There is simply no reason why one of skill in the art would remove the aspirin from formulations of Close, which were developed specifically for NSAIDs, and replace it with a benzimidazole compound, particularly since Henriksen has already addressed the problem of acid sensitivity for these compounds.

Furthermore, Close teaches a dispersing aid, such as an alkali metal phosphate salt or an amino acid, is included in the formulations to aid in disruption of enteric coating in the intestines. This goes against the teaching of Henriksen, discussed above, that "When this technique is used in accordance with the invention, there is no need to use any alkaline compounds or salts for further stabilization of the benzimidazole." This provides further evidence that one of skill in the art would not have sought to replace the aspirin in the formulations of Close with a benzimidazole compound from Henriksen.

Accordingly, Applicants maintain that claims 10, 11, 19 and 20 are not unpatentable over Close in view of Henriksen, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1 and 4-21 are now in condition for allowance, early notice of which would be appreciated. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Date: January 19, 2010

Respectfully submitted,

By: /Kenneth M. Zeidner, Reg. No. 64700/
Kenneth M. Zeidner
Reg. No. 64,700
Attorney for Applicants

Dr. Reddy's Laboratories, Inc.
200 Somerset Corporate Blvd.
Seventh Floor
Bridgewater, NJ 08807-2862
Tel. No.: 908-203-6504
Fax No.: 908-203-6515